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PROMOTE PROTECT PROSPER
2600 Bull Street
Columbia, SC 29201-1708

June 15, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Comments on Proposed Rule 21 CFR Parts 16 and 900, "State Certification of Mammography Facilities"

The South Carolina Department of Health and Environmental Control (SC DHEC) intends to submit an application next year for approval as a certification agency. In light of that, there are several statements that are of concern in Part IV, "Analysis of Impacts," as printed in the Federal Register on March 30, 2000.

1) Inspection support functions of the FDA has been defined as things such as inspector training, equipment calibration, and data and information transfer services. The inspection support functions that the FDA provides are the same, regardless of whether the facility is located in an SAC or non-SAC state. Therefore, the cost that the FDA associates with these functions should be the same, regardless of whether the facility is located in an SAC or non-SAC state. There should be no change in this fee because of states shifting into the SAC program. The functions are the same, regardless of SAC status, so the fee charged should be the same, regardless of SAC status.

2) The analysis does not consider that a state may have costs associated with the performance of MQSA inspections that are not currently being recovered from the contract with the FDA that the state may want to recover from facilities if it becomes a certifying agency. We currently do not recover 100% of our costs associated with participation in the MQSA inspection program. However, we would want to include these costs in the calculation of a fee charged to a facility if South Carolina becomes a SAC state. This would decrease any potential savings that may be realized by a facility in the state.

3) The analysis does not adequately explain how the figure of $509 was arrived at. It is stated that the initial fee was set at $509, with no justification of how that fee was determined. The "Analysis of Impacts" should justify that fee or itemization of FDA costs that went into determining the fee should be made available. To date, such an itemization has not been available.

Thank you for consideration of these comments. I appreciate the opportunity to comment on the regulations. If you have any questions, please call me at (803) 737-7418.

Sincerely,

Pamela M. Dukes

Pamela M. Dukes, Director
Division of Electronic Products
Bureau of Radiological Health

99N-4578

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cc: Wendy A. Taylor, Desk Officer

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